

## 6.0 510(k) Summary

### Submitter's Name / Contact Person

AUG 10 2006

Timothy J. Kappers, MBA, RAC  
Director, Quality Systems, Regulatory & Clinical Affairs  
Vital Images, Inc.  
5850 Opus Parkway, Suite 300  
Minnetonka, MN 55343

### General Information

|  |  |
|--|--|
| <b>Device Trade Name</b>                   | ViTALConnect™ 4.0 - Medical Image Processing Software                                |
| <b>Common / Usual Name</b>                 | System, Image Processing, Radiological   |
| <b>Classification</b>                      | 892.2050 Picture Archiving and Communications System (LLZ; Class II)                 |
| <b>Identification of Predicate Devices</b> | ViTALConnect System- formally The iConnection System (K040876)<br>Vital Images, Inc. |

### Device Description

The ViTALConnect system is a medical diagnostic device that allows the processing, review, analysis, communication and media interchange of multi-dimensional digital images acquired from a variety of imaging devices.

The ViTALConnect system provides multi-dimensional visualization of digital images to aid clinicians in their analysis of anatomy and pathology. The ViTALConnect system user interface follows typical clinical workflow patterns to process, review, and analyze digital images, including:

- Retrieve image data over the network via DICOM
- Display images that are automatically adapted to exam type via dedicated protocols
- Select images for closer examination from a gallery of up to six 2D or 3D views
- Interactively manipulate an image in real-time to visualize anatomy and pathology
- Annotate, tag, measure, and record selected views

- Output selected views to standard film or paper printers, or post a report to an Intranet Web server or export views to another DICOM device
- Retrieve reports that are archived on a Web server

## **Intended Use**

ViTALConnect, Version 4.0 is a medical diagnostic software system intended to process, analyze, review, and distribute multi-dimensional digital images acquired from a variety of imaging devices including: CT, MR, CR/DR/DX, SC, US, NM, PET, XA, and RF, etc. In addition, the ViTALConnect system has the following specific intended uses:

Advanced Vessel Analysis is an option within the ViTALConnect system intended to aid clinicians in the study and analysis of selected vessels, the inspection of circulatory anatomy, the quantification of stenosis, distance measurements and cross-sectional diameters, volume measurements, and assist in the planning and monitoring of vascular therapies. The feature operates with CT and MRI data.

Pet Visualization is an option within the ViTALConnect system that provides for the overlay, inspection, and measurement of two different image modalities (primarily directed at PET/CT). The option also includes the ability to measure Standard Uptake Values on PET datasets.

The overlay operation enables clinicians to obtain a better understanding of the joint information that would otherwise have to be compared separately. It is important to note that the clinician retains the ultimate responsibility for making pertinent diagnosis based on their standard procedures, including visual comparison of separate images.

Collaboration Mode is a capability within the ViTALConnect system that allows multiple users to collaboratively interact with ViTALConnect system features and tools.

## **Predicate Device Comparison**

The ViTALConnect 4.0 system and its predicate device allow for the analysis, communication and media interchange of digital images acquired from a variety of acquisition devices. All devices support the DICOM protocol for communication of images with other medical imaging devices.

## **Summary of Studies**

The software utilized was designed, developed, tested, and validated according to written procedures. These procedures specify individuals within the organization responsible for developing and approving product specifications, coding, testing, validating and maintenance.

The ViTALConnect 4.0 system will successfully complete integration testing/verification testing prior to Beta validation. Software Beta testing/validation will be successfully completed prior to release. In addition, potential hazards have been studied and controlled by a Risk Management Plan.

## **Conclusion**

The ViTALConnect 4.0 system has the same intended uses as the predicate device and has very similar technological characteristics. Minor technological differences do not raise any new questions regarding safety or effectiveness of the device. Thus, the ViTALConnect 4.0 system is substantially equivalent to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
9200 Corporate Blvd.  
Rockville MD 20850

AUG 10 2006

Vital Images, Inc.  
% Mr. Mark Job  
Responsible Third Party Official  
Regulatory Technology Services  
1394 25<sup>th</sup> Street NW  
BUFFALO MN 55313

Re: K062154  
Trade/Device Name: ViTAL Connect™ 4.0 Medical Image Processing Software  
Regulation Number: 21 CFR 892.2050  
Regulation Name: Picture archiving and communications system  
Regulatory Class: II  
Product Code: LLZ  
Dated: July 24, 2006  
Received: July 28, 2006

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.



*Protecting and Promoting Public Health*

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.


This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

|                |                                 |              |
|----------------|---------------------------------|--------------|
| 21 CFR 876.xxx | (Gastroenterology/Renal/Urology | 240-276-0115 |
| 21 CFR 884.xxx | (Obstetrics/Gynecology)         | 240-276-0115 |
| 21 CFR 894.xxx | (Radiology)                     | 240-276-0120 |
| Other          |                                 | 240-276-0100 |

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

### 3.0 Intended Use Statement

510(k) Number (if known): K062154

Device Name: ViTALConnect™ 4.0 Medical Image Processing Software

ViTALConnect, Version 4.0 is a medical diagnostic software system intended to process, analyze, review, and distribute multi-dimensional digital images acquired from a variety of imaging devices including: CT, MR, CR/DR/DX, SC, US, NM, PET, XA, and RF, etc. In addition, the ViTALConnect system has the following specific intended uses:

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Collaboration Mode is a capability within the ViTALConnect system that allows multiple users to collaboratively interact with ViTALConnect system features and tools.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use             
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C. Hodgson  
(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
510(k) Number K062154

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